

Amendments to the Claims

The following listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1–89. (canceled)

90. (currently amended) A pharmaceutical dosage form for oral administration to a patient providing pulsed gastric release of methylphenidate comprising:

- a) a gastric retention vehicle composition comprising about 10 wt-% to about 75 wt-% superdisintegrant, about 2 wt-% to about 12 wt-% tannic acid, and about 20 to about 70 wt-% of a hydrogel, whereby the gastric retention vehicle composition ~~provides~~ includes a homogenous solid matrix and the percentages are calculated with respect to the matrix exclusive of other excipients and the methylphenidate,
- b) a plurality of first particles containing methylphenidate that are dispersed in the matrix, wherein the first particles contain methylphenidate ~~is released from the first particles into the stomach upon contact with gastric fluid~~, and
- c) a plurality of second particles containing methylphenidate that are dispersed in the matrix, wherein the second particles contain methylphenidate, wherein each of the second particles ~~are~~ is coated with a coating that is impermeable to methylphenidate and dissolves in gastric fluid, and, after a sufficient amount of the coating is dissolved, the methylphenidate is released from the second particles into the stomach causing the coating to be breached by the gastric fluid,

wherein, upon contact with gastric fluid the gastric retention vehicle composition expands to a sufficient degree such that the dosage form is retained ~~promote retention of the dosage form in the patient's stomach at least until methylphenidate is released from the second particles and wherein methylphenidate is released from the first particles into the stomach, and, thereafter, the coating of the second particles is breached and methylphenidate is released from the second particles into the stomach.~~

91. (currently amended) A pharmaceutical dosage form of claim 90 further comprising a plurality of third particles containing methylphenidate that are dispersed in the matrix, wherein each of the third particles having ~~is coated with~~ a coating that is impermeable to the

methylphenidate ~~that and~~ dissolves in gastric fluid causing the coating to be breached by the gastric fluid, wherein, after about 3 to 5 hours after release of methylphenidate from the second particles, and the methylphenidate is released from the third particles into the stomach after the methylphenidate is released from the second particles.

92. (previously presented) A pharmaceutical dosage form of claim 90 wherein the first particles are coated with a coating that delays release of the methylphenidate from those particles, with the proviso that the first particles and the second particles are not released at the same time.

93. (currently amended) A pharmaceutical dosage form for oral administration to a patient providing pulsed gastric release of methylphenidate comprising:

- a) a gastric retention vehicle composition comprising about 20 wt-% to about 70 wt-% of a hydrogel, about 10 wt-% to about 75 wt-% superdisintegrant and about 2 wt-% to about 12 wt-% tannic acid, the percentages calculated exclusive of other excipients or the methylphenidate,
- b) a first reservoir containing methylphenidate wherein methylphenidate is released from the first reservoir into the stomach upon contact of the dosage form with gastric fluid, and
- c) a second reservoir containing methylphenidate, wherein the second reservoir is coated with a coating that is impermeable to methylphenidate and dissolves in gastric fluid, and, after a sufficient amount of the coating is dissolved, the methylphenidate is released from the second particles into the stomach causing the coating to be breached by the gastric fluid,

wherein, upon contact with gastric fluid the gastric retention vehicle composition expands to a sufficient degree such that the dosage form is retained promote retention of the dosage form in the patient's stomach at least until methylphenidate is released from the second reservoir and wherein methylphenidate is released from the first reservoir into the stomach, and, thereafter, the coating of the second reservoir is breached and methylphenidate is released from the second reservoir into the stomach.

94. (currently amended) A pharmaceutical dosage form of claim 93 further comprising a third reservoir containing methylphenidate coated with a coating that is impermeable to methylphenidate and dissolves in gastric fluid causing the coating to be breached by the gastric fluid and methylphenidate to be released from the third reservoir about 3 to 5 hours

~~after release of methylphenidate from the second reservoir, wherein the methylphenidate is released from the third reservoir into the stomach after the methylphenidate is released from the second reservoir.~~

95. (original) A pharmaceutical dosage form of claim 93 wherein the first reservoir is coated with a coating that delays release of the methylphenidate from that reservoir.

96. (original) A pharmaceutical dosage form of claim 93 wherein the gastric retention vehicle composition and the reservoirs are encapsulated.

97–112. (canceled)

113. (previously presented) The pharmaceutical dosage form of claim 90, wherein the methylphenidate is released from the second particles into the stomach about 3 to about 5 hours after administration.

114. (previously presented) The pharmaceutical dosage form of claim 93, wherein the methylphenidate is released from the second reservoir about 3 to about 5 hours after administration.

115. (new) The pharmaceutical dosage form of claim 91, wherein the methylphenidate is released from the third particles into the stomach about 3 to about 5 hours after the methylphenidate is released from the second particles.

116. (new) A method of treating hyperactivity or attention deficit disorder comprising administering a therapeutically effective amount of methylphenidate in the pharmaceutical dosage form of claim 90 to a patient in need thereof.

117. (new) A method of treating hyperactivity or attention deficit disorder comprising administering a therapeutically effective amount of methylphenidate in the pharmaceutical dosage form of claim 93 to a patient in need thereof.

118. (new) The pharmaceutical dosage form of claim 90, wherein the coating comprises (i) a film coating agent selected from the group consisting of water soluble resins, water insoluble resins, waxes, lipids, enteric resins, or (ii) a polymeric coating substance.

119. (new) The pharmaceutical dosage form of claim 93, wherein the coating comprises

polymethacrylate, or a mixture of hydrophilic and hydrophobic film forming agents.

120. (new) The pharmaceutical dosage form of claim 93, wherein the hydrophilic film forming agent is selected from the group consisting of methyl cellulose, hydroxypropyl methylcellulose, cellulose phthalate, cellulose acetate phthalate, and polyvinyl alcohol.

121. (new) The pharmaceutical dosage form of claim 93, wherein the hydrophobic film forming agent is selected from the group consisting of ethyl cellulose, cellulose acetate, hydroxypropyl methylcellulose phthalate, polyvinyl alcohol maleic anhydride copolymers, β -pinen polymers rosin, partially hydrogenated rosin, and glycerol esters of rosin.

122. (new) The pharmaceutical dosage form of claim 90, wherein the superdisintegrant is selected from the group consisting of cross-linked carboxymethylcellulose sodium, sodium starch glycolate, and cross-linked polyvinyl pyrrolidone.

123. (new) The pharmaceutical dosage form of claim 93, wherein the superdisintegrant is selected from the group consisting of cross-linked carboxymethylcellulose sodium, sodium starch glycolate, and cross-linked polyvinyl pyrrolidone.

124. (new) The pharmaceutical dosage form of claim 90, wherein the hydrogel is hydroxypropyl methyl cellulose or a mixture of hydroxypropyl methyl cellulose and hydroxypropyl cellulose or a cross-linked acrylate polymer.

125. (new) The pharmaceutical dosage form of claim 93, wherein the hydrogel is hydroxypropyl methyl cellulose or a mixture of hydroxypropyl methyl cellulose and hydroxypropyl cellulose or a cross-linked acrylate polymer.